This summary of the 510(k) pre-market notification for the Smith & Nephew Saphyre Bipolar Ablation Probes is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

MAY 2 3 2003

Manufacturer
Smith & Nephew, Inc
Endoscopy Division
3700 Haven Court
Menlo Park, CA 94025

Contact Person(s)
Deborah Connors
Smith & Nephew, Regulatory Affairs Manager
150 Minuteman Road
Andover, MA 01810

Device Name
Saphyre Bipolar Ablation Probes, Class II device (21 CFR 878.4400)

Generic/Common Name
Electrosurgical cutting and coagulation device and accessories

Device Description
The Smith & Nephew Saphyre Bipolar Ablation Probes are single-use, bipolar, electrosurgical devices intended for coagulation of soft tissues. The Saphyre Bipolar Ablation Probes consist of an insulated shaft, an insulated power electrode, a return electrode, and a handle. Saphyre Bipolar Ablation Probes with Suction incorporate suction capability for the removal of tissue from the surgical site.

Technological Characteristics
Smith & Nephew is requesting clearance to modify the device's existing general indications for use to more specific indications for use. There was no actual physical change to the device as a result of the proposed modified indications for use statement and, therefore, no changes to the technological characteristics.

Indications for Use
The Smith & Nephew Saphyre Bipolar Ablation Probes, in combination with the Smith & Nephew Vulcan EAS Generator, are intended for general surgical use, including orthopedic and arthroscopic applications for resection, ablation, excision of soft tissue, hemostasis of blood vessels, and in coagulating soft tissue in joints including but not limited to the knee, shoulder, wrist, hip, etc. Arthroscopic surgery could include a variety of procedures.

Predicate Device(s)

•	Indication for Use:	Vulcan Electrosurgical Probes	K000691, cleared May 15, 2000
		ArthroCare ArthroWands	K011083, cleared June 28, 2001
•	Design:	Bipolar Ablation Probes	K991218, cleared September 13, 1999

Substantial Equivalence Determination

The modified indications for use for the Smith & Nephew Saphyre Bipolar Ablation Probes are substantially equivalent to the predicate devices. This determination is based on the following:

1. The indications for use, as modified for the Saphyre Bipolar Ablation Probes, and design are equivalent to that of the predicate devices and;
2. No new risks have been introduced as a result of the modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Ms. Linda Guthrie
Manager Regulatory Affairs and Compliance
Smith & Nephew, Inc.
Endoscopy Division
3700 Haven Court
Menlo Park, California 94025

Re: K031371
Trade/Device Name: Smith & Nephew Saphyre Bipolar Ablation Probes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 25, 2003
Received: April 30, 2003

Dear Ms. Guthrie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K031371

Device Name: Smith & Nephew Saphyre Bipolar Ablation Probes

Indications for Use: The Smith & Nephew Saphyre Bipolar Ablation Probes, in combination with the Smith & Nephew Vulcan EAS Generator, are intended for general surgical use, including orthopedic and arthroscopic applications for resection, ablation, excision of soft tissue, hemostasis of blood vessels, and and in coagulating soft tissue in joints including but not limited to the knee, shoulder, wrist, hip, etc. Arthroscopic surgery could include a variety of procedures, as listed in the table below.

Examples of Arthroscopic Surgery

All Joints	Debridement (tendon, cartilage, fracture), Plica Removal, Resection, Synovectomy, Bursectomy, Ablation, Excision of Soft Tissue (scar tissue), Hemostasis of Blood Vessels, Coagulating Soft Tissues (ligament, articular cartilage), and Chondroplasty.
Knee	Meniscectomy, Meniscal Cystectomy, PCL/ACL Debridement, Notchplasty, Lateral Release, Labral Tear.
Shoulder	Acromioplasty, Rotator Cup Debridement, Subacromial Decompression, CA Ligament Resection, and Capsular Release.
Wrist	Triangular Fibrocartilage (TFC).

for Mark N. Miller
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031371

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)